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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Hirokazu Nishimura

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EXAMINER

SYED, ATIA K

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/667,865	Applicant(s) NISHIMURA ET AL.	
	Examiner ATIA SYED	Art Unit 4185	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 January 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) 15-22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>See Continuation Sheet</u> . | 6) <input type="checkbox"/> Other: _____ |

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :11/01/2007, 04/18/2008, 07/29/2008, 04/02/2007, 08/31/2006, 09/12/2005, 09/22/2003.

DETAILED ACTION

Response to Restriction Requirement

Applicant's election without traverse of specie A regarding the diagnostic support system is acknowledged.

Claims 15-22 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b) as being drawn to a non-elected invention.

Election was made without traverse, filed on 01/09/2009.

Specification

The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-14 are rejected as failing to define the invention in the manner required by 35 U.S.C. 112, second paragraph.

The claim(s) are narrative in form and replete with indefinite and functional or operational language. The structure which goes to make up the device must be clearly and

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positively specified. The structure must be organized and correlated in such a manner as to present a complete operative device. The claim(s) must be in one sentence form only. Note the format of the claims in the patent(s) cited.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-10 and 13-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Graham et al. (WO 98/58338), herein after referred to as Graham.

Regarding claim 1, Graham disclose a diagnostic support apparatus comprising:

diagnostic support content storage means (fig 2, page 12, lines 27-28; server with database) for storing a plurality of diagnostic support contents for providing diagnostic support;

selection means (fig 3a, select practice routine 560; page 15, lines 6-7; physician can select from a drop down menu) for selecting a desired diagnostic support content from the plurality of diagnostic support contents stored in the diagnostic support content storage means;

information acquisition means (fig 11A, angiography routine; page 26, line 15- page 28, line 19) for acquiring diagnostic information concerning at lest one of a patient, an examination, and an image from a medical system;

diagnostic support information creating means (evaluation software 340; page 13, lines 25-29; fig 3b, evaluation routine 600, generates diagnostic support information based on the information selected by the physician in the earlier routines) for creating diagnostic support information on the basis of the diagnostic support content selected by the selection means and the diagnostic information acquired from the medical system; and

diagnostic support display means (display 312, page 13, line 4) for displaying the diagnostic support information created by the diagnostic support information creation means.

Applicant is advised that the claim contains several examples of functional language which describes the intended use or purpose of the device, rather than further limiting the structure of the invention. Under MPEP 2114, such language will not overcome the prior art where no structural differences are recited.

Examples of such language in the claim include “for storing a plurality of diagnostic support contents”, “for selecting a desired diagnostic support content”, “for acquiring diagnostic information concerning a patient.....” etc.

Regarding claim 2, Graham disclose a diagnostic support apparatus wherein:

the diagnostic support apparatus is constituted by a plurality of computers connected to each other through a line, and further comprises (fig 2; page 12, lines 27-29);
transmission means for transmitting the stored diagnostic support content, and
reception means for receiving the diagnostic support content transmitted from the transmission means (fig 2; page 12, line 24-page 13, line 12); and

the diagnostic support information creating means creates diagnostic support information on the basis of diagnostic information acquired from the medical system and the diagnostic support content received by the reception means (page 17, lines 5-9; the diagnostic support system acquires information provided by the physician including test results and provides recommendations based on the received information and the data stored in the database 230).

Regarding claim 3, Graham disclose a diagnostic support apparatus further comprising:

diagnostic support content creating means for creating diagnostic support content (evaluation software 340; page 13, lines 25-29);

transmission means for transmitting a diagnostic support content created by using the diagnostic support content creating means; and

reception means for receiving the diagnostic support content transmitted from the transmission means (fig 2; page 12, line 24-page 13, line 12).

Regarding claim 4, Graham disclose a diagnostic support apparatus further comprising:

diagnostic support content creating means storage means for storing the diagnostic support content creating means (server, or the memory of local computer hard drive or floppy disk drive; page 12, lines 24-32-page 13, lines 1-17);

transmission means for transmitting diagnostic support content creating means stored in the diagnostic support content creating means storage means; and

reception means for receiving the diagnostic support content creating means transmitted from the transmission means, and creates diagnostic support content by using the received diagnostic support content creating means (fig 2; page 12, line 24-page 13, line 12).

Regarding claim 5, Graham disclose a diagnostic support apparatus wherein:

the diagnostic support content creating means further comprises storage means for storing first diagnostic support content (the first diagnostic support content could either be stored on the local drive of the computer, if a single computer is used or on the server if a plurality of computers are connected via a network; page 13, lines 16-17 and lines 23-24); and

creates second diagnostic support content by using the first diagnostic support content and the diagnostic information (figs 5-6B; page 18, lines 9-23; fig 11; page 27, lines 22-24-page 28, lines 1-4; if there is an already existing diagnostic content for a given patient then the new diagnostic content builds on the already stored diagnostic content for that patient).

Regarding claim 6, Graham disclose a diagnostic support apparatus wherein:

the diagnostic support content storage means and the transmission means constitute a diagnostic support server (fig 2; server 220, page 12, line 28); and

the information acquisition means, the reception means, the diagnostic support information creating means, and the diagnostic support information display means constitute a diagnostic support execution terminal (fig 2; local computers 250; page 12, line 29; page 13, lines 3-5, evaluation software 340; page 13, lines 26-29).

Regarding claim 7, Graham disclose a diagnostic support apparatus further comprising:

a diagnostic support content creating terminal including diagnostic support content creating means for creating the diagnostic support content, and transmission means for transmitting, to the diagnostic support content server, diagnostic support content created by using the diagnostic support content creating means (local computer 250; page 17, lines 3-9; the physician uses his local workstation with preloaded evaluation software to create diagnostic support content which could then be transmitted to the server 220).

Regarding claim 8, Graham disclose a diagnostic support apparatus wherein the apparatus comprises:

a diagnostic support content creating means server including diagnostic support content creating means storage means for storing the diagnostic support content creating means, and transmission means for transmitting the diagnostic support content creating means to the diagnostic support content providing terminal (page 13, lines 25-29; the diagnostic support content creating means is stored on the server which is transmitted to the local terminals via a network); and

the diagnostic support content creating terminal comprises diagnostic support content reception means for receiving the transmitted diagnostic support content creating means (the local computers access the evaluation software and the database via a network; page 12, lines 26-33; page 13, lines 23-29); and

creates diagnostic support content by using the received diagnostic support content creating means (page 13, lines 18-24; the diagnostic support content is created by receiving the evaluation software form the server).

Regarding claim 9, Graham disclose a diagnostic support apparatus wherein the apparatus comprises:

detection means for detecting that diagnostic support content stored in the diagnostic support content storage means is at least updated or added (page 18, lines 5-6; whenever new information is added to the diagnostic support content, it is automatically detected and stored by the diagnostic support content storage); and

transmits the diagnostic support content on the basis of a detection result obtained by the detection means (page 18, lines 9-19; physician can save and load workups to the database 230 at any time, once a new evaluation file is saved, it's detected by the administrative software and sent to the database 230 for future use; page 17, lines 6-9).

Regarding claim 10, Graham disclose a diagnostic support apparatus wherein the diagnostic support content creating terminal comprises:

information acquisition means for acquiring diagnostic information concerning at least one of a patient, an examination, and an image from a medical system (fig 11A, angiography routine; page 26, line 15-page 28, line 19); and

storage means for storing first diagnostic support content (server, or the memory of local computer hard drive or floppy disk drive; page 12, lines 24-32-page 13, lines 1-17); and

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creates second diagnostic support content by using the first diagnostic support content and the diagnostic information (figs 5-6B; page 18, lines 9-23; fig 11; page 27, lines 22-24-page 28, lines 1-4; if there is an already existing diagnostic content for a given patient than the new diagnostic content builds on the already stored diagnostic content for that patient).

Regarding claim 13, Graham disclose a diagnostic support method of providing diagnostic support comprising:

- a step of acquiring diagnostic support content (page 13, lines 23-24; the physician acquires previously stored diagnostic support contents form the database 230 which stores all the information regarding patients and diagnosis; page 17, lines 6-9);

- a step of inputting diagnostic information concerning at least one of a patient as a diagnostic support target, an examination, and an image (page 13, lines 20-22);

- a step of creating diagnostic support information using the diagnostic support content and the diagnostic information (evaluation software, physician inputs patient information along with all the symptoms, risk factors and test results and the evaluation software returns diagnostic support information, abstract);

- a step of displaying the diagnostic support information (page 13, lines 20-22).

Regarding claim 14, Graham disclose a diagnostic support method further comprising:

- a step of creating the diagnostic support content (the system allows the physicians to create a diagnostic support content, abstract); and

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a step of transmitting the diagnostic support content to another computer (the diagnostic support content could be transmitted to the server or the administrative computer; page 13, line 9).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 11 and 12 are rejected under 35 U.S.C 103(a) as being unpatentable over Graham et al. (WO 98/58338) in view of Ema et al. (US 5, 779, 634) herein after referred to as Ema.

Regarding claims 11 and 12, Graham disclose the claimed invention except the diagnostic support apparatus comprises characteristic value calculator for images.

However, Ema disclose a diagnostic support information creating means comprises characteristic value calculation means for calculating a characteristic value from a medical image contained in the diagnostic support information (column 17, lines 47-55) , and creates diagnostic support information based on the characteristic value calculated by the characteristic value calculation means (column 17, lines 44-46).

It would have been obvious to one of ordinary skill in the art at the time of invention to modify the teaching of Graham with Ema since Ema suggest an improved method for evaluation of x-ray and other image based reports using a CAD system (Ema, column 1, lines 49-57).

Regarding claim 12, the diagnostic support system disclosed by Graham as modified by Ema comprises:

an information creating means further comprises identification/classification means (Graham, evaluation software comprises identification/classification means; page 21, lines 9-23); and

creates diagnostic support information based on an identification/classification result using the characteristic value calculated by the characteristic value calculation means (the evaluation software generates diagnostic support information based on the classification of the diagnosed disease, as modified above the system could further incorporate characteristic values to generate diagnostic support information).

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The following references are cited for disclosing related limitations of the

applicant's claimed and disclosed invention.

Yamada, Shinichi et al. (EP 487110 A2), **Segal, Elliot A. et al.** (US 20010041991 A1), **Filler, Aaron G.** (US 20010051881 A1), **Eglington, Thor** (US 20020091687 A1), **Schuetze; Hinrich et al.** (US 6567797 B1).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Atia Syed (Tel No. 571-270-7134). The examiner can normally be reached on Monday-Friday, 8:30AM to 3:30PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terrell Mckinnon can be reached on 571-272-4797. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/A. S./

01/16/2009

Examiner, Art Unit 4185

/Terrell L Mckinnon/

Supervisory Patent Examiner, Art Unit 4185

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